

EXHIBIT B

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

BIONPHARMA INC.,

Defendant.

C.A. No. 21-1286-LPS

C.A. No. 21-1455-LPS

**DEFENDANT BIONPHARMA’S FIRST SET OF
REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendant Bionpharma Inc. (“Bionpharma”), submits its First Set of Requests for Production of Documents and Things directed to Plaintiff Azurity Pharmaceuticals, Inc. (“Plaintiff” or “Azurity”), and request that Plaintiff produce the documents and things requested herein within thirty (30) days of service to the offices of Taft, Stettinius & Hollister LP, 111 E. Wacker Drive, Suite 2800, Chicago, IL 60601, or at such other time and place as may be mutually agreed upon by the parties, in accordance with the instructions and definitions below.

DEFINITIONS AND INSTRUCTIONS

Bionpharma hereby incorporates by reference, as though fully set forth herein, the Definitions and Instructions in Bionpharma’s First Set of Requests for the Production of Documents and Things (Nos. 1-91), and in Bionpharma’s First Set of Interrogatories (No. 1), both served November 20, 2019 in connection with the *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.) cases.

I. SUPPLEMENTAL DEFINITIONS

1. The term “Alkem” means to Alkem Laboratories Ltd., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Alkem also means the defendant in *Silvergate Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, Case No. 19-cv-2100 (D. Del.), and any other Related Patent Litigation.

2. The term “Amneal” means Amneal Pharmaceuticals LLC, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Amneal also means the defendant Amneal in *Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, CA No. 19-cv-678 (D. Del.); *Silvergate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, CA No. 20-cv-01255 (D. Del.), and any other Related Patent Litigation.

3. The term “Annora” means to Annora Pharma Private Limited, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Annora also means the defendant in *Silvergate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, Case No. 20-cv-753 (D. Del.) and *Silvergate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, Case No. 21-cv-196 (D. Del.), and any other Related Patent Litigation.

4. The term “Aurobindo” means Aurobindo Pharma Ltd. and/or Aurobindo Pharma USA, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest as well as any of their present or former officers,

directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. The term “Aurobindo” also means the defendants in *Azurity Pharmaceuticals, Inc. v. Aurobindo Pharma Ltd.*, CA No. 21-cv-1707 (D. Del.), and any other Related Patent Litigation.

5. The term “Azurity” means Plaintiff Azurity Pharmaceuticals, Inc., and (i) all respective predecessors-in interest and successors-in-interest, including but not limited to CutisPharma, Inc. and Silvergate Pharmaceuticals, Inc.; (ii) all respective past or present corporate parents, subsidiaries, affiliates, divisions, officers, directors, employees, agents, consultants, investigators, attorneys, and representatives; (iii) any other person acting on their behalf or on whose behalf they have acted or are acting; or (iv) any other person or entity otherwise subject to their control or which controls or controlled them. Where applicable, this definition shall include all persons having a former or current ownership interest in any of the Enalapril Liquid Patents or Related Patent Application(s).

6. The term “Azurty-CoreRx LSA” shall mean the Litigation Settlement Agreement between Azurity and CoreRx.

7. The term “CoreRx” means to CoreRx, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, including but not limited to NovaQuest Capital Management, etc. as well as any of CoreRx’s present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. CoreRx also means defendant CoreRx in *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.); *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 8:21-cv-2515 (M.D. Fla.) and any other case related to Epaned.

8. The Term “Enalapril Liquid Patents” means, collectively, the First, Second, and Third Wave Patents.

9. The term “First Wave Patents” means ’008, ’442, ’745, and ’987 patents.

10. The term “First Wave Suits” means *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.).

11. The term “MMSA” shall mean the November 2020 Master Manufacturing Supply Agreement between Bionpharma and CoreRx.

12. The term “NovaQuest” means to NovaQuest Capital Management LLC, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf.

13. The term “Plaintiff” means Azurity, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, including but not limited to CutisPharma, Inc. and Silvergate Pharmaceuticals, Inc., etc. as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Where applicable, this definition shall include all persons having a former or current ownership interest in any of the Enalapril Liquid Patents or Related Patent Application(s).

14. The term “Related Patent Applications” means any and all patent applications or patents (U.S. and foreign) corresponding to, or claiming priority from, the Enalapril Liquid Patents whether or not abandoned and whether or not issued, or to which the Enalapril Liquid Patents,

whether or not abandoned and whether or not issued, claim priority or any and all applications or patents (U.S. and foreign) directed to enalapril liquids.

15. The term “Related Patent Litigation” means any lawsuit filed by or against Plaintiff or any other entity or person concerning or relating to any enalapril solution, Epaned and/or the Enalapril Liquid Patents or Related Patent Applications.

16. The term “Second Wave Patents” means U.S. Patent Nos. 10,786,482 B2 (“’482 patent”); 10,918,621 B2 (“’621 patent”); 10,772,868 B2 9 (“’868 patent”)

17. The term “Second Wave Suit” means *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.).

18. The term “Third Wave Patents” means U.S. Patent Nos. 11,040,023 B2 (“’023 patent”) and 11,141,405 (“’405 patent”).

19. The term “Third Wave Suits” means instant actions, *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 21-1286-LPS, 21-1455-LPS (D. Del.).

REQUESTS FOR PRODUCTION

1. All documents and things concerning U.S. Patent Application No. 16/991,575 (’621 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

2. All documents and things concerning U.S. Patent Application No. 17/150,587 (’023 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

3. All documents and things concerning U.S. Patent Application No. 17/228,024 ('405 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

4. All documents and things concerning any discussion, consideration or decision by Plaintiff regarding whether to file, re-file, or prosecute any patent application relating to the Enalapril Liquid Patents and/or Related Patent Applications.

5. All references cited or referred to during the prosecution of the Second Wave Patents, Third Wave Patents, or Related Patent Applications, including all references cited on the face of the Second Wave Patents and Third Wave Patents.

6. All documents and things concerning any prior use, patent, publication, or other prior art that was cited, referred to, or relied upon, during the prosecution of the Second Wave Patents, Third Wave Patents, or Related Patent Applications.

7. All documents and things concerning any communications, patent office filings, or judicial or regulatory filings concerning Second Wave Patents, Third Wave Patents, or Related Patent Applications.

8. All documents, communications and things relating to the Examples set forth in the Enalapril Liquid Patents, Related Patent Applications, and any declarations, including but not limited to declarations from inventor(s) of the Enalapril Liquid Patents and Related Patent Applications, submitted to the USPTO, including but not limited to, all data relating to any testing and any laboratory notebooks related to the Examples.

9. All documents and things concerning any novelty, patentability, validity, infringement, state-of-the-art, unenforceability or right-to-use search, investigation, report,

opinion, study, or analysis, whether formal or informal, that relates to the Second Wave Patents or to the Third Wave Patents.

10. All documents supporting or undermining any assertions of secondary considerations of non-obviousness that Plaintiff intends to raise, intended to raise, or have raised in the Third Wave Suits, including but not limited to, proof of nexus, profit margins and marketing expenditures.

11. Documents sufficient to show the ownership interest of NovaQuest in Azurity and CoreRx.

12. Documents sufficient to show organizational structure of, and corporate relationship between, Azurity, NovaQuest, and CoreRx.

13. Documents sufficient to show the ownership of Azurity, NovaQuest, and CoreRx.

14. All documents and things concerning relationships, agreements, and communications between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to the Enalapril Liquid Patents, Related Patent Applications, Epaned, and/ or NDA No. 208686.

15. Any settlement agreements between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to Enalapril Liquid Patents, Related Patent Applications, Epaned, and/or NDA No. 208686.

16. All documents and things referring or relating to or constituting any assignment, license, contract, authorization, agreement, stipulation, settlement, or negotiations involving Plaintiff in regard to any legal right to any of the Enalapril Liquid Patents or Related Patent Applications, or to any legal right to any of the alleged inventions or products referred to in

Plaintiff's Complaint in the Third Wave Suits, including, but not limited to, enalapril solution and/or Epaned.

17. All documents and things referring or relating to or constituting any assignment, license, contract, authorization, agreement, stipulation, settlement, or negotiations involving Plaintiff and Amneal, Aurobindo, Annora, and/or Alkem in regard to any legal right to any of the Enalapril Liquid Patents or Related Patent Applications, or to enalapril solution and/or Epaned.

18. All documents and things concerning any relationship that exists or has existed between Azurity and any other defendant in the Related Epaned Litigations pertaining to enalapril and/or any of the Enalapril Liquid Patents, including, but not limited to, any co-marketing agreements or authorized generic agreements.

19. All documents and things referring or relating to any valuations of the indemnification granted by Azurity to CoreRx in the settlement agreement between Azurity and CoreRx regarding Third Wave Patents.

20. All documents and things concerning the Azurity-CoreRx LSA, including any drafts of the Azurity-CoreRx LSA.

21. All documents and communications relating to actual or potential generic competition to Epaned.

22. All documents and communications with NovaQuest relating to Bionpharma, Bionpharma's ANDA Product, or any actual or potential competition to Epaned.

23. All documents and communications with NovaQuest relating to CoreRx's relationship with Bionpharma, including documents and communications pertaining to the MMSA.

24. All documents and communications with CoreRx relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, the MMSA, the Azurity-CoreRx LSA, NovaQuest, and any other enalapril ANDA filer.

25. All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of CoreRx, including Messrs. Nailesh Bhatt, Vern Davenport, Jeff Edwards, and Frank Leo.

26. All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of Azurity, including Messrs. Nailesh Bhatt, Richard Blackburn, Vern Davenport, Jeff Edwards, Frank Leo, Amit Patel, and Dave Ritchie.

27. All documents and things, including communications between Azurity and NovaQuest, relating to NovaQuest's decision, negotiation, or agreement to take an ownership interest in CoreRx.

28. All documents, communications, and things relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.

29. All documents, communications, and things between Azurity and NovaQuest relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.

30. All documents and things pertaining to Azurity's decision to voluntarily dismiss *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.) and *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 21-2515-VMC-SPF (M.D. Fla.).

31. All documents and things related to Plaintiff's sales and marketing expenditure for Epaned.

32. All sales data relating to Epaned generated or dating from the first day of commercial sale of the product to the present.

33. All profit and sales projections for Epaned.

34. All profit and sales projections for Epaned taking into account any contemplated or actual generic competition to Epaned.

35. All documents and things concerning the projected and/or actual damages to Azurity caused by launch of Bionpharma's ANDA Product.

36. All documents and things concerning the projected and/or actual damages to Azurity caused by launch of Annora's ANDA Product.

37. All documents and things concerning the projected and/or actual damages to Azurity caused by the launch of any enalapril liquid generic to Epaned.

38. All documents since the first commercial launch of Epaned sufficient to describe the gross and net sales, market share, gross and net profits; sales and profit forecasts; advertising, promotion, presentation, description, and/or explanation of Epaned, including, but not limited to, materials concerning market research regarding Epaned, customer/physician surveys, sales representative materials, and all market analyses.

39. All documents and things sufficient to show actual gross and net profits from Epaned sales.

40. All documents and communications (including from consultants, market analysts, attorneys, or other third parties), including any opinions of counsel, concerning the strength(s) or

weakness(es) of any of the Enalapril Liquid Patents and/or the merits or expected outcome of any of the First Wave Suits, Second Wave Suit, Third Wave Suits and/or Related Patent Litigations.

41. All documents and things concerning any opinions of counsel concerning any of the Enalapril Liquid Patents, the First Wave Suits, the Second Wave Suit, the Third Wave Suits, and/or Related Patent Litigations.

42. All documents and things concerning the value of, damages for infringement, and/or royalties for licenses in connection with Enalapril Liquid Patents and Related Patent Applications.

43. All documents and things concerning the value of, damages for infringement, and/or royalties for licenses in connection with the Third Wave Patents.

44. Documents sufficient to identify each drug that competes with Epaned.

45. Documents sufficient to identify each hypertension treatment that competes with Epaned.

46. Documents sufficient to identify each symptomatic heart failure treatment that competes with Epaned.

47. Documents sufficient to identify each asymptomatic left ventricular dysfunction treatment that competes with Epaned.

48. Documents sufficient to describe the cost, availability, and distribution of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

49. All documents and things relating to the gross and net sales, market share, gross and net profits; sales and profit forecasts; advertising, promotion, presentation, description, and/or

explanation of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

50. Documents sufficient to show the pricing, whether proposed, offered or actual, of all marketed dosages and forms of Epaned.

51. All documents and things relating to any price changes considered or implemented for Epaned in response to any perceived or actual competition.

52. All strategic planning documents for Epaned, including each marketing plan, 5-year plan, or market analysis for Epaned, and any documents or communications concerning such strategic planning documents.

53. All documents relating to any market in which Epaned competes, including all documents relating to the market share of Epaned and/or any product or therapy that actually or potentially competes with Epaned, any competitive analysis of any product or therapy that actually or potentially competes with Epaned, and the impact (including impact on sales (in dollars or unit volume) and/or profits) on Azurity of any product or therapy that actually or potentially competes with Epaned.

54. All documents concerning the advertising, promotion or marketing of Epaned, including but not limited to, advertisements, drafts of advertisements, market research, advertising budgets, results of focus groups or consumer surveys, letters to healthcare providers and direct-to-consumer advertising.

55. One copy of each detail aid, visual aid, product monograph and/or piece of promotional or professional literature used by Plaintiff's representatives to detail or promote Epaned to physicians and/or other health care professionals.

56. All detail and/or sample audits, including but not limited to IMS data, relating to Epaned.

57. Any market research, physician surveys, or prescriptions data analysis for Epaned or for any treatment that competes with Epaned or that is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

58. All studies, analyses, compilations or reports of physicians' impressions or opinions concerning Epaned.

59. All analyses, memoranda, charts, studies or other data recording or reporting the market share of Epaned, whether actual or projected.

60. All documents and things concerning any planned or implemented response to generic competition for Epaned.

61. All documents and communications relating to strategies or attempts to prevent or delay generic competition to Epaned.

62. All documents and communications relating to generic competition to Epaned, including evaluation of ANDA filers.

63. All documents concerning competition for the sale of any enalapril product.

64. All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of First Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;

- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of First Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

65. All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of Second Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;
- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of Second Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

66. All documents, communications, and things relating to Azurity's decision to sue, and to maintain its suit against, Bionpharma for alleged infringement of Third Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;
- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of Third Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

67. All documents and things referenced in Azurity's Rule 26(a)(1) disclosures.

68. All documents and things Azurity intends to rely on to prove its claims in the Third Wave Suits.

Dated: March 21, 2022

/s/ Megan C. Haney

John C. Phillips, Jr. (#110)

Megan C. Haney (#5016)

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CERTIFICATE OF SERVICE

I, Megan C. Haney, hereby certify that on March 21, 2022, a copy of Defendant Bionpharma First Set of Requests for Production of Documents and Things was served upon the following counsel of record in the manner indicated below:

VIA EMAIL

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